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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,250	08/21/2001	Wenbin Dang	GPT-029.01	6514

29755 7590 10/29/2003

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

18

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,250

Applicant(s)

DANG ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 2, 2003 has been entered.

The outstanding rejection under 35 USC 112, second paragraph is withdrawn in view of the amendments filed September 2, 2003.

The outstanding rejection under 35 USC 102(b) is withdrawn in view of the applicant's remarks filed September 2, 2003 stating that Lostritto does not teach a composition that lidocaine HCl is sparingly soluble in the composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7, 10, 12-18, 21, 23, and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "said biocompatible oil has a viscosity below about 140 cSt at 20°C" in claim 5 renders the claim indefinite as to the biocompatible oil encompassed

Art Unit: 1617

thereby. It is not clear what biocompatible oil would have such viscosity. The specification does not list any example of oil with such viscosity. Therefore, the metes and bounds of the claim are not defined.

The limitation "said biocompatible oil has a viscosity below about 45 cSt at 20°C" in claim 7 renders the claim indefinite as to the biocompatible oil encompassed thereby. It is not clear what biocompatible oil would have such viscosity. The specification does not list any example of oil with such viscosity. Therefore, the metes and bounds of the claim are not defined.

The limitation "said biocompatible oil has a dielectric constant below about 20" in claim 10 renders the claim indefinite as to the biocompatible oil encompassed thereby. It is not clear what biocompatible oil would have such dielectric constant. The specification does not list any example of oil with such dielectric constant. Therefore, the metes and bounds of the claim are not defined.

The limitation "said biocompatible oil has a dielectric constant below about 5" in claim 12 renders the claim indefinite as to the biocompatible oil encompassed thereby. It is not clear what biocompatible oil would have such dielectric constant. The specification does not list any example of oil with such dielectric constant. Therefore, the metes and bounds of the claim are not defined.

Claims 13-18, 21, 23, and 28-29 recite the limitation "said biocompatible oil, and all other biocompatible oils" in 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 merely recites "a biocompatible oil".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15, 17, 19-26 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Takagishi et al. (US Patent 4,339,463).

Takagishi et al. teaches a suspension for filling the capsule comprising sesame oil and aspirin, in which the amount of sesame oil can be up to 84% and the amount of aspirin can be up to 44% (See col. 5 and 6, Table 3-6).

Claims 1 and 27-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Samejima et al. (JP 10001441, English abstract is provided).

Samejima et al. teaches a local anesthetic composition may contain lidocaine and sesame oil, which is in an oil mixture in an amount of 70-100% (See the abstract).

The printed instructions recited in the claims lend no patentable weight to claims that drawn to composition because they do not impart a structure-functional relationship to the herein claimed composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1617

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takagishi et al. (US Patent 4,339,463) as applied to claims 1, 13-15 above.

Takagishi et al. teaches a suspension for filling the capsule comprising sesame oil and aspirin, in which the amount of sesame oil can be up to 84% and the amount of aspirin can be up to 44% (See col. 5 and 6, Table 3-6).

Takagishi et al. does not teach the amount of the oils as at least 90% or 95% in weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the weight ratio of the oil components in Takagishi et al. to the herein claimed amount.

One of ordinary skill in the art would have been motivated to adjust the weight ratio of the oil components in Takagishi et al. to the herein claimed amount. It is known that the BaSO₄ component added to the capsule of Takagishi as for X-ray demonstration of the release of the drug (See col. 2, line 49-53). Therefore, one of

Art Unit: 1617

ordinary skill in the art would have remove the BaSO₄ component when prepare the liquid filler for the capsule, which make the sesame oil component to be around 90% (consider first example in Table 6: the composition contains the sesame oil component as $424 + 34 = 458\text{mg}$, and aspirin as 50mg). Furthermore, the optimization of result effect parameters (e.g., the amount of excipients) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to claims 1-41 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

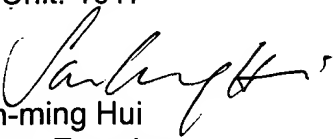
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Application/Control Number: 09/934,250

Page 7

Art Unit: 1617


San-ming Hui
Patent Examiner
Art Unit 1617